K002486

NOV - 9 2000

Summary of Safety and Effectiveness
for
Precimed Trauma System

This safety and effectiveness summary for the Precimed Trauma System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
Patrick Berdoz
50 Devyn Drive
Chester Springs, PA 19425

Date Prepared: August 4, 2000

Contact Person :
Patrick Berdoz
50 Devyn Drive
Chester Springs, PA 19425
Telephone: (610) 524-8300

2. Tradename: Precimed Trauma System
Common Name: Fracture Fixation System
Classification Name: Single/ multiple component metallic bone fixation appliances and accessories (888.3030)
Smooth or threaded metallic bone fixation fasteners (888.3040)

3. Predicate or legally marketed devices which are substantially equivalent:

- Osteo Auto Compression Plating System (S &N Richards)
- Internal Fixation System (Synthes)
- Internal Fixation System (Howmedica)

4. Description of the device :

The Precimed Trauma System is a complete system of implants and instruments designed to provide the orthopedic surgeon with the devices necessary to achieve optimal fracture fixation. It consists of compression plates, cancellous and cortical bone screws, cannulated screws and specialty bone plates.

Materials: The devices are manufactured from 316 LVM stainless steel per ASTM and ISO standards.
Function: The system functions to provide immediate stability and temporary fixation during the natural healing process following fractures.

5. Intended Use:

The Precimed Trauma System is indicated for use in the treatment of pelvic, small and long bone fractures.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Precimed Trauma System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2000

Mr. Patrick Berdoz
50 Devyn Drive
Chester Springs, Pennsylvania 19425

Re: K002486
Trade Name: Precimed Trauma System
Regulatory Class: II
Product Codes: HRS
Dated: August 4, 2000
Received: August 14, 2000

Dear Mr. Berdoz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) :

Device Name : Precimed Trauma System

Indications For Use :

The Precimed Fracture Fixation System is indicated for use in pelvic, small and long bone fracture fixation.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ____ OR Over-the-counter use _____
(PER 21 CFR 801.109)

(optional format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002486